

REMARKS

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. §112, first paragraph; and claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. §103. Applicants believe that the rejections are improper based on at least the reasons set forth below.

With respect to the rejection of claims 11-14, 16-19 and 21-26 under 35 U.S.C. §112, first paragraph, the Patent Office alleges that these claims fail to comply with the written description requirement. More specifically, the Patent Office alleges that the claim limitation “nutritional composition is not a fermented nutritional composition” has no support in the specification as filed. Applicants believe that this rejection is improper.

“[T]o comply with the description requirement of 35 U.S.C. §112, first paragraph . . . ; all that is required is that the application reasonably convey to the person skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.” *Forssmann v. Matsuo*, 23 U.S.P.Q.2d 1548, 1550 (B.P.A.I. 1992), *aff’d*, 991 F.2d 809 (Fed. Cir. 1993). “[I]psis verbis disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.” *Fujikawa v. Wattanasin*, 39 USPQ 2d 1895, 1904 (Fed. Cir. 1996) citing *In re Edwards*, 196 USPQ 465, 467 (CCA 1978).

Applicants believe that the claim limitation at issue is sufficiently described in Applicants’ specification such that one skilled in the art would reasonably understand that Applicants had possession of same at the time of filing the application. At the outset, the specification provides that the nutritional composition may be fermented to obtain a sufficient quantity of *lactobacilli*. See, specification, page 4, lines 32-33. Clearly, one skilled in the art would understand this disclosure to mean that the nutritional compositions may or may not be fermented. Indeed, Applicants’ specification further supports this meaning. For example, Examples 1 and 4 described in vitro tests that used *lactobacilli* on its own. See, Example 1, page 8, line 35 to page 9, line 10; Example 4, line 19 to page 11, line 19. Moreover, the claims as originally filed cover a nutritional composition with *lactobacilli* without restriction as to whether or not it is fermented, thus conveying that the claimed invention can cover both forms, that is, a fermented nutritional composition or an unfermented nutritional composition. Based on at least these reasons, Applicants believe that one skilled in the art would reasonably ascertain that the written description requirement has been satisfied.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

In the Office Action, claims 11-14, 16-19 and 21-26 are rejected under 35 U.S.C. §103. More specifically, claims 11, 12, 16-19, 21, 23 and 24 are rejected in view of Sellars and Yaeshima; and claims 11-14, 16-19 and 21-26 are rejected in view of Sellars and Yaeshima and further in view of U.S. Patent Nos. 5,494,664 and 5,478,302. The Patent Office primarily relies on the Sellars reference and thus relies on the remaining cited art to remedy the deficiencies of this reference. Applicants believe that the obviousness rejections are improper.

Of the pending claims at issue, claims 11, 19 and 23 are the sole independent claims. Claim 11 recites a method for the treatment or prophylaxis of calcium deficiencies in a mammal having or at risk of calcium deficiency. The method includes enterally administering to the mammal a nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in the intestines of the mammal wherein the nutritional composition is not a fermented nutritional composition.

Claim 19 recites a method for increasing absorption of calcium from a diet. The method includes enterally administering to a mammal that requires increased calcium absorption, a nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal wherein the nutritional composition is not a fermented composition. Claim 23 recites a method for improving the absorption of calcium in a mammal. The method includes enterally administering to the mammal that requires increased calcium absorption a nutritional composition that includes one or more *Lactobacillus* bacteria capable of arriving in a living state in intestines of the mammal wherein the nutritional composition is not a fermented nutritional composition.

In contrast, Applicants believe the cited art, even if combinable, is distinguishable from the claimed invention. With respect to the primary Sellars reference, the focus of this reference relates to fermented products. Indeed, Sellars provides “that when fermented dairy products containing *lactobacilli* are consumed, the bioavailability or mineral absorption is increased.” See, Sellars, page 102, paragraph 2, lines 1-4. Further, Sellars provides that it is the metabolite of a fermented dairy product, i.e., lactic acid, that influences the rate of absorbed minerals. See, Sellars, page 102, paragraph 2, lines 4-5 and lines 15-17. Moreover, the Patent Office even admits that Sellars fails to provide the absorption of the mineral calcium. Therefore, Sellars on

its own is clearly distinguishable from methods for the treatment or prophylaxis of calcium deficiencies in a mammal, methods for increasing absorption of calcium in a diet, and methods for improving the absorption of calcium in a mammal that utilizes an enterally administered nutritional composition that is not fermented and includes *lactobacillus* bacteria capable of arriving in a living state in the intestines of the mammal as required by the claimed invention.

Further, Applicants do not believe that the remaining cited art can be relied on solely to remedy the deficiencies of Sellars. At the outset, the Yaeshima reference relates to the use of *bifidobacterium longum* and not *lactobacillus*. The focus of Yaeshima is to use *bifidobacterium longum* in combination with an oligosaccharide, i.e., lactulose, which promotes whey Ca absorption and thereby increases the strength of bone. See, Yaeshima, page 41, column 2, paragraph 1, lines 2-5 and see Figure 13. Clearly, this teaches away from the claimed invention. Indeed, the nutritional compositions as claimed can provide an effect to promote calcium absorption in the absence of an oligosaccharide as further supported in the specification, for example, on page 5 at lines 23-28. Therefore, even if combinable, Sellars and Yaeshima are deficient with respect to the claimed invention.

Further, U.S. Patent Nos. 5,494,664 and 5,578,302 cannot be used alone or in combination to remedy the deficiencies of Sellars and Yaeshima. At the outset, the emphasis of both of these patents does not even relate to mineral absorption, let alone calcium absorption. For example, the '664 patent primarily relates to *bifidobacterium* that can adhere to and competitively exclude pathogenic bacteria responsible for diarrhea from intestinal cells. See, '664 patent, Abstract; and column 6, lines 24-29. Like the '664 patent, the focus of the '302 patent relates to the competitive exclusion of pathogenic bacteria. See, '302 patent, column 1, lines 49-52. In '302, the compositions are administered for therapeutic or prophylactic treatment of the stomach and particularly for the treatment of gastritis or ulcers of the stomach or the pylorus. See, '302 patent, column 1, lines 56-62. Indeed, Applicants have demonstrated that the ability of a strain to adhere to intestinal cells is effectively not relevant to the benefit of increased mineral absorption. See, Specification, for example, page 9, lines 26-29.

What the Patent Office has done is to rely on hindsight reasoning in support of the obviousness rejections. Clearly, this is not proper. As previously discussed, the Sellars reference fails to recognize the significance of a fermented nutritional product with *lactobacilli* for purposes of mineral absorption, let alone calcium absorption. Again, Yaeshima does not

even relate to *lactobacillus* but rather focuses on *bifidobacterium* in combination with lactulose. Moreover, the remaining cited references emphasize the competitive exclusion of pathogenic bacteria to treat stomach ulcers (see, '302 patent) and diarrhea (see, '604 patent) as previously discussed. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify Sellars in view of Yaeshima and the remaining two references allegedly disclosed.

Based on at least these reasons, Applicants believe that the cited art is distinguishable from the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

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